

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

**Angela Soito**

Atty. Docket: 005284.00226

Examiner: Unknown

Group Art Unit: Unknown

Serial No.: To Be Assigned  
(Division of Serial No.: 09/916,647)

Filed: November 20, 2003

For: Cytological Evaluation Of Breast Duct Epithelial Cells Retrieved By Ductal Lavage

**INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

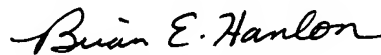
Pursuant to their duty of good faith and candor as set forth in 37 C.F.R. § 1.56(a) Applicants submit herewith the references cited on the attached PTO-1449 forms.

Copies of these references are not submitted herewith, but can be found in parent application file U.S. Serial No. 09/916,647.

Applicants respectfully request that the Examiner consider these references in connection with the search of the prior art required by 37 C.F.R. § 1.104.

It is believed that no fee is required to ensure consideration of the cited references by the Examiner. However, if a fee is deemed necessary, the Commissioner is authorized to charge our Deposit Account No. 19-0733.

Respectfully submitted,



Brian E. Hanlon  
Reg. No. 40,449

Date: 11/20/03  
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Sheet	1	of	4
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**Compleat if Known**

Application Number	TBA
Filing Date	November 20, 2003
First Named Inventor	Angela Soito et al.
Group Art Unit	TBA
Examiner Name	TBA
Attorney Docket Number	005284.00226

## U.S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04.

<sup>3</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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Sheet 2

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**OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Sartorius, Breast Fluid Cells Help In Early Cancer Detection, JAMA, Vol. 224(6), pp 823-827, 1973	
		Papanicolaou et al, "Exfoliative Cytology of the Human Mammary Gland and Its Value in the Diagnosis of Cancer and Other Diseases of the Breast", Cancer, pp 377-409, March/April, 1958	
		Petrakis, "Physiological, biochemical, and cytological aspects of nipple aspirate fluid", Breast Cancer Research and Treatment, Vol. 8, pp 7-19, 1986	
		Petrakis, "Studies on the epidemiology and natural history of benign breast disease and breast cancer using nipple aspirate fluid", Cancer Epidemiology, Biomarkers and Prevention, Vol. 2, pp 3-10, Jan/Feb 1993	
		Petrakis, "Nipple Aspirate Fluid in Epidemiological Studies of Breast Disease", Epidemiologic Reviews, Vol. 15, pp 188-195, 1993	
		Sauter et al, "Nipple aspirate fluid: a promising non-invasive method to identify cellular markers of breast cancer risk", British Journal of Cancer, Vol. 76(4), pp 494-501, 1997	
		Imayama et al, Cancer, Vol. 78, pp 1229-1234, 1996	
		Love & Barsky, Breast-duct endoscopy to study stages of cancerous breast disease, Lancet, Vol. 348, pp 997-999, 1996	
		Goodson WH & King EB, Chapter 4: Discharges and Secretions of the Nipple, The Breast: Comprehensive Management of Benign and Malignant Diseases, 2 <sup>nd</sup> Ed., Vol. 2, Bland & Kirby eds. W.B. Saunders Co., Philadelphia, PA, pp 51-74, 1998	
		Wrensch et al, Breast Cancer Incidence in Women with Abnormal Cytology in Nipple Aspirates of Breast Fluid, American Journal of Epidemiology, Vol. 135 (2), pp 130-41, 1992	
		Wrensch et al. Breast Cancer Research and Treatment, "Factors associated with obtaining nipple aspirate fluid: Analysis of 1428 women and literature review", Vol. 15, pp 39-51, 1990 Sauter et al, Prostate-Specific Antigen Levels in Nipple Aspirate Fluid Correlate with Breast Cancer Risk, Cancer Epidemiology, Biomarkers & Prevention, Vol. 5(12), pp 967-70, 1996	
		Wrensch et al, Breast Fluid Cholesterol and Cholesterol B-Epoide Concentrations in Women with Benign Breast Disease, Cancer Res., Vol. 49, pp 2168-2174, 1989	
		King et al, Nipple Aspirate Cytology for the Study of Breast Cancer Precursors, JNCL, Vol. 71(6), pp 1115-1121, 1983	
		Sartorius et al, Cytologic Evaluation of Breast Fluid in the Detection of Breast Disease, J. Natl Cancer Inst, Vol. 59, pp 1073-1080, 1977	

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		Frykberg and Masood Copeland EM 3d. Bland KI., (Ductal carcinoma in situ of the breast) Surgery, Gynecology & Obstetrics, Vol. 177(4), pp 425-40, 1993	
		King et al, Cytometry, "Analytic Studies of Foam Cells From Breast Cancer Precursors", Vol. 5, pp 124-130, 1984	
		King et al, A.J.C.P., "Cellular Composition of the Nipple Aspirate Specimen of Breast Fluid", Vol. 64, pp 728-738, 1975	
		Masood et al, The Missing Link: A "Pap Smear" For Early Breast Cancer Detection and Prevention, The Breast Journal, Vol. 5, pp 1-2, 1999	
		Petrakis et al, Studies on the Epidemiology and Natural History of Benign Breast Disease and Breast Cancer Using Nipple Aspirate Fluid, Cancer Epidemiology, Biomarkers and Prevention, Vol. 2, pp 3-10, 1993	
		Sartorius et al, Cytologic Evaluation of Breast Fluid in the Detection of Breast Disease, NCI, Vol. 59, pp 1073-1080, 1977	
		Fabian et al, J. Cellular Biochemistry, Biomarker and Cytologic Abnormalities in Women at High and Low Risk for Breast Cancer, Vol. 17G, pp 153-160, 1993	
		Porter-Jordan and Lippman, "Overview of the biological markers of breast cancer", Hematology/Oncology Clinics of North America, Vol. 8(1), pp 73-100, 1994	
		Sauter et al, Prostate-Specific Antigen Levels in Nipple Aspirate Fluid Correlate with Breast Cancer Risk, Cancer Epidemiology, Biomarkers & Prevention, Vol. 5(12), pp 967-70, 1996	
		JIN, Zhang et al. "Study of Tumor Markers in Mammary Ductal Lavage for Early Detection of Breast Carcinoma. I. Chinese Tumor Clinical Medicine, Vol. 23, Issue 6, pp. 381-385, 1996 (with English Translation attached)	

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		King, E. B. et al, "Analytic Studies Of Foam Cells From Breast Cancer Precursors", Cytometry, Vol. 5, No. 2, pp 124-130, 1984	
		Sneige, Nour et al., "Fine needle aspiration cytology of ductal hyperplasia with and without atypia and ductal carcinoma in situ", Human Pathology, Vol. 25, No. 5, pp 485-492, 1994	
		Love, Suan M. et al, "Breast-duct endoscopy to study stages of cancerous breast disease", Lancet (North American Edition), Vol. 348, No. 9033, pp 997-999, 1996	
		King, E. B. et al, "Cellular Composition Of The Nipple Aspirate Specimen Of Breast Fluid Part 1 The Benign Cells, American Journal of Clinical Pathology, Vol. 64, No. 6, pp 728-738, 1975	
		Porter-Jordan, Kathleen et al, "Overview of the biologic markers of breast cancer", Hematology-Oncology Clinics of North America, Vol. 8, No. 1, pp 73-100, 1994	
		Evron, Ella et al, "Detection of breast cancer cells in ductal lavage fluid by methylation-specific PCR", Lancet (North American Edition), Vol. 357, No. 9265, 2001	

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